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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,171	05/04/2006	Ulrike W. Klueh	MTI/101/PC/US	4607

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EXAMINER	
SCHULTZ, JAMES	

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
11/29/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,171	KLUEH ET AL.	
	Examiner	Art Unit	
	James D. (Doug) Schultz	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1,2,9,14-16,19,25,28,37,39,51,52,59,66,68-73 and 75-90* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,2,9,14-16,19,25,28,37,39,51,52,59,66,68-73 and 75-90* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed September 21, 2011 has been considered. Rejections and/or objections not reiterated from the previous office action mailed March 21, 2011 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 9, 14-16, 19, 25, 28, 37, 39, 51, 52, 59, 66, 68-73, and 75-90, filed March 15, 2010, are pending, and are the subject of the present Official action.

Specification

The use of the trademark Nafion has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 2, 9, 14-16, 19, 25, 51, 66, 70, 71, 78-87, 89, and 90 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention is drawn to "an implant system comprising a sensor implanted in biological tissue…". This phrasing is considered to embrace nonstatutory subject matter, since the claim is drawn to "the implant system" system itself, and since the sensor is required to be implanted in biological tissue. Thus, the claim embraces both the sensor and the biological tissue into which it has been implanted. Furthermore since the claim is drawn to the implant system that comprises the sensor that is already implanted in biological tissue, the claim embraces a human that has the claimed sensor/ biological matrix/plurality of cells. While it is clear that the specification does not appear to specifically contemplate a human as an implant system, the specification also does not provide a definition for what an "implant system" embraces, and it is not unreasonable to suggest that a human biological system that comprises the claimed implant would broadly constitute an "implant system". Removal of the phrase "implanted in biological tissue" would be remedial.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 9, 14-16, 19, 25, 28, 37, 39, 51, 52, 59, 66, 68-73, and 75-90 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification

in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The most recent amendment of September 21, 2011 adds claim language to each claim specifying that the recited sensor extends "functionality by at least one day". Applicants have pointed to paragraphs 145, 148, and 171 as providing support; however, a review of these paragraphs does not reveal *ipsis verbis* support. Furthermore, while *ipsis verbis* support is not required, and while there may exist support for the concept of extending functionality generally (a finding neither verified nor attested to presently), no support is found at all for the specific numerical figure of "at least one day" as now recited. Should applicants disagree, applicants are invited to point out with particularity by page and line number where such support exists for the specific numerical range of extending functionality by "at least one day".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 9, 14-16, 19, 25, 28, 37, 39, 51, 52, 59, 66, and 68-73, and 75-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lamberti et al. (hereinafter "Lamberti"; WO 2003/072157), Ward et al. (hereinafter "Ward"; WO 1997/019344), and Nelson et al. (hereinafter "Nelson"; U.S. Patent Number 6,596,296).

The claims are drawn to an implant system comprising a glucose having an outer surface including an analyte sensitive coating, and further comprising a biological matrix containing cells, wherein the cells extend sensor functionality by at least one day.

Lamberti teaches a medical device which is exemplified as a glucose sensor with a bioactive hydrogel-coated biomaterial containing growth factors to direct tissue organization and vascularization of a medical device. Lamberti teaches that the bioactive hydrogel coatings are expected to reduce the avascular capsule surrounding an implanted device, and improve the intimate contact between surrounding tissues and active device elements and hence the performance of devices such as implanted glucose sensors for closed-loop control of diabetes. Lamberti does not teach matrigel as a biological matrix, or VEGF expressing cells embedded therein.

Ward teaches an amperometric glucose sensor that is covered by a membrane which is semi-permeable to the analyte of interest. Ward teaches an approach for minimizing fibrotic capsule interference with sensor performance, i.e., increasing sensor longevity, by promoting vascularity in the capsule so that the sensor can continue to have access to blood analytes. Ward

teaches that this can be accomplished by vascular growth factors incorporated in a matrix around the sensor so that the growth factors are slowly released into the surrounding tissue. The released growth factors enhance capillary growth in the collagenous capsule which forms around the implanted sensor. Retention of capillary perfusion by the capsule enhances sensor function by continuously providing the sensor access to the patient's blood analyte. Ward teaches that one example of a capillary growth factor includes vascular endothelial growth factor (VEGF). Ward does teach

Nelson teaches the use of matrigel to coat medical devises, wherein the matrigel is embedded with VEGF.

It would have been obvious to provide a glucose sensor with matrigel that expresses VEGF from cells embedded in matrigel. Ward teaches glucose sensors with a semipermeable membrane having a biological matrix that expresses VEGF or a fibrotic inhibitor. Thus Ward is considered to teach the need to inhibit fibrosis as well as to promote device integration and vascularization using VEGF. Lamberti teaches an amperometric glucose sensor comprising the use of a matrix that releases growth factors for tissue integration, and is thus considered to teach the need for using growth factors for tissue integration. Nelson teaches the use of a biological matrix, which may be matrigel, containing VEGF to coat medical devices to promote tissue integration. Thus, Lamberti teaches an amperometric glucose sensor comprising a matrix to promote integration, Ward teaches a similar invention, but uses VEGF to promote integration, and and Nelson teaches VEGF containing matrigel to coat medical devices generally. Thus, it would have been obvious to use a VEGF containing matrigel to coat an amperometric glucose sensor. Using a cell to express said VEGF would have been obvious to one of ordinary skill in

the arts, since VEGF expressing cells are known in the art (official notice taken here), and since one of ordinary skill would have understood that matrigel is optimized to provide a solid support for cell growth, and since one of ordinary skill in the art would have had a reason to use cells for such a purpose since cell expression would provide a longer release than VEGF protein embedded biological matrix would have. Accordingly, in the absence of evidence to the contrary, one of ordinary skill in the art would have considered the invention as a whole to have been *prima facie* obvious at the time the invention was made.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. (Doug) Schultz whose telephone number is (571)272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James D. (Doug) Schultz/
Primary Examiner, Art Unit 1633